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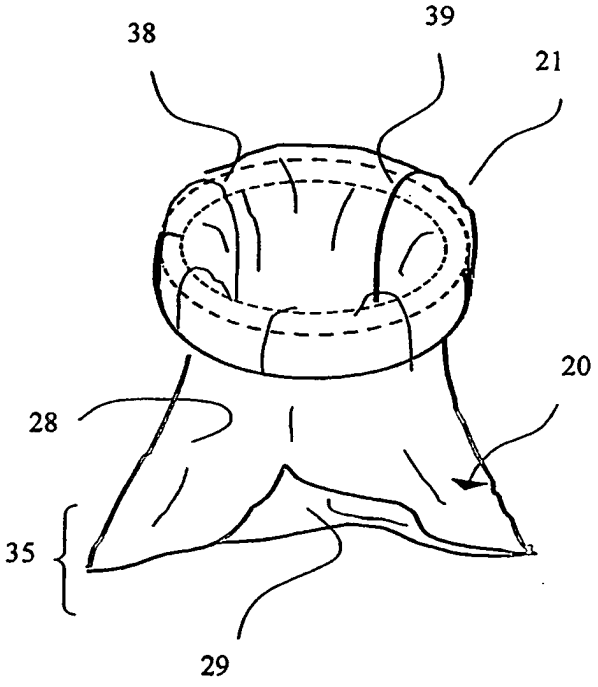
(54) Title: ATRIOVENTRICULAR HEART VALVE AND MINIMALLY INVASIVE DELIVERY SYSTEMS THEREOF



(57) Abstract: An atrioventricular valve intended for attaching to a circumferential valve ring and papillary muscles of a patient comprising a singular flexible membrane (20) of tissue or synthetic biomaterial, the valve having a sewing ring (10), an anterior cusp (52) and a posterior (51), wherein the anterior cusp and said posterior cusp are an integral part of a continuum from the singular membrane without sutured commissure between remote ends of the cusps and wherein texture elements (75) secured at edge portions of the cusps configured to extend the texture elements for connection to papillary muscles in a ventricle cavity when the sewing ring is sut

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DESCRIPTION

Atrioventricular Heart Valve and Minimally Invasive Delivery Systems Thereof

Field of the Invention

The invention herein described relates to cardiac atrioventricular valves and minimally invasive delivery systems thereof.

Background of the Invention

During normal physiological functions, the human heart valve opens up in response to the pressure of blood flow on its leaflets. The human heart valve also closes under the pressure exerted on the same leaflets when blood flow retrogrades. This physiological function of the heart valve prevents the backflow of blood in the heart. When the body is under no physical stress and the heart is beating at a normal resting state of about 70 beats per minute, the leaflets open by separation from one another and close by apposing each other, approximately 38 million times per year. It can be surmised that under stressful conditions or higher heart rates, the number of separations and appositions increases, as well as the force of impact between the leaflets.

Disease, congenital malformation, aging or trauma conditions can cause a natural heart valve to dysfunction. This may occur due to the decay, degeneration or disruption of the heart valve and/or its components. To restore proper functionality necessary for the continuation of life, a prosthetic heart valve is used to repair or replace the natural heart valve. Characteristics of a typical prosthetic heart valve may include hemodynamic performance, thrombogenicity, durability and ease of surgical implantation.

The shape of the leaflet and surrounding elements of a valve or a prosthetic valve apparatus is dependent on the function of the heart. In the past, numerous publications have taught that the valve shape directs the function of the heart. However, new paradigms have explained that it is the function of the heart that actually directs and defines the formation of the specific shape or form of the valve. This principle of "Form Follows Function" can now be used to produce new valvular mechanisms that more closely mimic the function of the native human heart valve.

An atrioventricular valve, otherwise known as the mitral valve (in the left side of the heart) or the tricuspid valve (in the right side of the heart), is part of a continuum

(referred to herein as the valve apparatus) that extends from the myocardium or muscular wall of the lower chambers, through the papillary muscles, the tendinous rope-like elements known as *chordae tendinae*, and the leaflets. There is a tricuspid valve apparatus in the right ventricular chamber, and more importantly the mitral valve apparatus within the left ventricular chamber, the pumping function of which provides the systemic flow of blood through the aorta to keep all tissues of the body supplied with oxygenated blood necessary for cellular function and life. These leaflets form a ring-like structure, known as the annulus, that is part of the heart's skeleton.

During a cardiac cycle, the valve apparatus functions as part of a unit composed of multiple interrelated parts, including the ventricular and atrial walls, the valve leaflets, the fibrous skeleton of the heart at the atrioventricular ring, and the subvalvular apparatus. The subvalvular apparatus includes the papillary muscle within the ventricle, and the *chordae tendinae* which connect the papillary muscle to the valve leaflets.

The present practice of valvular surgery when the mitral valve alone is replaced after excision of the diseased mitral valve apparatus ignores the necessary contribution of the ventricular function. The ventricle and the apparatus work in unison to provide proper pumping to systemic or pulmonary circulation and proper arrest of blood return to the chambers of the atria.

Aortic and pulmonary valves have been replaced with simple trileaflet chemically treated biological valves obtained from animals, or bileaflet mechanical valves without extreme deficiencies in valvular or cardiac function. This is not the case when mitral or tricuspid valves are replaced and the necessary involvement of *chordae tendinae* and muscular elements of the chamber wall are not united to function in harmony with the valve leaflets. Those valves used in the aortic position cannot alone replace the mitral valve apparatus without anatomical and functional compromise.

Therefore, this requirement to maintain the continuum is of an absolute imperative nature for the mitral or tricuspid valve apparatuses.

In the past, attempts to generate the needed structure have met with difficulties. Thus, Aranguren Duo in U.S. Pat. No. 4,261,342, Gross in U.S. Pat. No. 5,662,704, and Gross in U.S. Pat. No. 5,824,067, incorporated herein by reference in their entirety, resort to use of a pig heart (porcine, swine) mitral valve to which a covering material is attached to the papillary heads around the *chordae tendinae*, in the form of a tube that provides an extension in order to fit and affix the valve to the papillary muscle remnants of the human heart after the diseased valve and subvalvular structure is excised and removed from the

heart. This tube has to be trimmed until the proper dimension is found to connect the leaflets to the papillary remnants. However, trimming the tube during the surgery is necessary because the relation between annular size and chordal length are different in animal than in human hearts.

Frater in U.S. Pat. No. 5,415,667 teaches an apparatus with a trapezoidal annulus possessing a rigid side. To this trapezoidal annulus are attached four separate leaflets joined together by sutures to provide an occluding surface to the flow of blood during the systolic or ejection phase of the cardiac cycle. The chordae are separate chords attached by sewing to the edge portion of the leaflets. At times, these are integral in the four separate cusps and are each attached by sewing the other three cusps. All four cusps and their respective chordal attachment portions and flange portions are formed as separate components for fitting to a basic ring element having a trapezoidal opening. The sutured attachment portions render the cusp less flexible as compared to a natural cusp without sutures.

Machuraju in U.S. Pat. No. 5,554,184 discloses cutting two leaflets that are then sutured together to form a bileaflet valve. Similarly, Deac in U.S. Pat. No. 5,344,442 and U.S. Pat. No. 5,500,015, entire disclosures of which are incorporated herein by reference, teaches a means for cutting sections of biological material and joins them by sutures to form a bileaflet mitral valve. The sutured joint portion becomes stiff and less flexible. There is a clinical need to fabricate a bileaflet or trileaflet valve with sutureless joint portion or commissure; preferably to have the valve made from a singular membrane of tissue or artificial sheet.

All of the aforementioned patents teach of a form made by stitching various sections of material and expecting that the form will be able to profile the function. This leads Cox in U.S. Pat. No. 6,270,526 to pronounce his principle of "Form Follows Function." He notices that the human fetus while in its early stages (about 25 days of gestation) *in utero* that further exhibits tubular connections between the fetal heart gestational developments that will produce the structure. This "Form Follows Function" is the paradigm that must be used in order to fabricate a heart valve that will very closely identify with the human heart valve.

Current Options for Tissue Heart Valve Replacement

Most tissue valves are constructed by sewing the leaflets of pig aortic valves to a stent to hold the leaflets in proper position as a stented porcine valve. They may also be

constructed by removing valve leaflets from the pericardial sac of cows or horses and sewing them to a stent as a stented pericardium valve. The stents may be rigid or slightly flexible and covered with cloth (usually a synthetic material sold under the trademark Dacron™ or Teflon™) and attached to a sewing ring for fixation to the patient's native tissue. In one embodiment, the porcine, bovine or equine tissue is chemically treated to alleviate any antigenicity.

A stentless valve prosthesis generally comprises a biological valve having a suture ring, anchoring skirts at the commissures of the valve, and an outer polyester covering. A stentless valve prosthesis secured or supported to the native valve annulus and leaflets reduces tissue stress as the flexible valve prosthesis adapts and conforms to the native valve, so that durability and resistance to wear and calcification are improved.

The main advantage of tissue valves is that they do not cause blood clots to form as readily as do the mechanical valves, and therefore, the tissue valves do not typically require lifelong systemic anticoagulation measures. However, the presence of the stent and sewing ring prevents the tissue valve from being anatomically accurate in comparison to a normal human heart valve.

Principles of Tissue Heart Valve Construction

Cox in U.S. Pat. No. 6,270,526, No. 6,092,529, No. 5,824,063, No. 5,713,950, and No. 5,480,424, incorporated herein by reference in their entirety, teaches the "Function Follows Form" principles of tissue heart valve construction. Under the best of circumstances (i.e., replacement of the aortic valve), the construction of artificial tissue valves has been based on the concept that if the artificial valve can be made to approximate the anatomy (form) of the native valve, then the physiology (function) of the artificial valve will also approximate that of the native valve. This is the concept that "Function Follows Form." For example, the manufacturers of all artificial porcine valves first re-create the form of a native human aortic valve by: 1) harvesting a porcine aortic valve, 2) fixing it in glutaraldehyde or other suitable fixatives to eliminate antigenicity, and 3) suturing the porcine valve to a stent to hold the three leaflets in place. In other words, the primary goal in the construction of these artificial valves is to reproduce the form of the human aortic valve as closely as possible. The assumption is made that if the artificial valve can be made to look like the human aortic valve, it will function like the human aortic valve (i.e., proper function will follow proper form). The same assumption is also followed for commercially available pericardial valves.

In the case of mitral or tricuspid valve replacement, even the dubious concept of "function follows form" has been discarded since the same artificial valves that are designed to look like the aortic valve are used to replace the mitral and tricuspid valves. In other words, no attempt at all is made to reproduce even the form of these native valves, much less so their function.

Thus, in the case of artificial valves to be used for aortic valve replacement, the dubious concept of "function follows form" has dictated the construction of all artificial tissue valves during the 30 years of their development and use. Even worse, no discernable underlying concept at all has been used in terms of the artificial valves used to replace the mitral and tricuspid valves.

The "Function Follows Form" concept has several limitations and appears to be a fundamental shortcoming which underlies the present construction of all artificial tissue valves. In the first place, it simply is not possible to recreate the exact anatomy (form) of a native heart valve utilizing present techniques. Although homograft (human cadaver) and porcine aortic valves have the gross appearance of native aortic valves, the fixation process (freezing with liquid nitrogen, and chemical treatment, respectively) alters the histological (microscopic) characteristics of the valve tissue. Porcine and bovine pericardial valves not only require chemical preparation (usually involving fixation with glutaraldehyde), but the leaflets must be sutured to cloth-covered stents in order to hold the leaflets in position for proper opening and closing of the valve. A recent advance has been made in this regard by using "stentless" porcine valves that are sutured or supported directly to the patient's native tissues for aortic valve replacement, but the problem of chemical fixation remains. In addition, these stentless artificial valves cannot be used for mitral or tricuspid valve replacement.

Perhaps the major limitation of the "Function Follows Form" concept is that no efforts have been made previously to approximate the form of either the mitral valve or the tricuspid valve. If animal tissue valves are used to replace either of these native valves, the tri-leaflet porcine aortic valve prosthesis or the tri-leaflet bovine pericardial valve prosthesis is normally used. In doing so, even the faulty concept of "Function Follows Form" is ignored, since there are no artificial valves available for human use that approximate the anatomy (form) of the native mitral or tricuspid valves.

Percutaneous Intercostal Penetration

Various surgical techniques may be used to repair a diseased or damaged valve, including annuloplasty (contracting the valve annulus), quadrangular resection (narrowing the valve leaflets), commissurotomy (cutting the valve commissures to separate the valve leaflets), shortening mitral or tricuspid valve *chordae tendinae*, reattachment of severed atrioventricular valve *chordae tendinae* or papillary muscle tissue, and decalcification of valve and annulus tissue. Alternatively, the valve may be replaced, by excising the valve leaflets of the natural valve, and securing a replacement valve in the valve position, usually by suturing the replacement valve to the natural valve annulus.

A conventional procedure for approaching the left atrium is by intravascular catheterization from a femoral vein through the cardiac septal which separates the right atrium and the left atrium. This intravascular procedure is not only dangerous and tedious because of its long, tortuous route, but is also of limited use because of the catheter size suitable for insertion intravascularly.

Sterman et al. in U.S. Pat. No. 6,283,127, entire contents of which are incorporated herein by reference, discloses a device system and methods facilitating intervention within the heart or great vessels without the need for a median sternotomy or other form of gross thoracotomy, substantially reducing trauma, risk of complication, recovery time, and pain for the patient. Using the device systems and methods of the invention, surgical procedures may be performed through percutaneous penetrations within intercostal spaces of the patient's rib cage, without cutting, removing, or significantly displacing any of the patient's ribs or sternum. The device systems and methods are particularly well-adapted for heart valve repair and replacement, facilitating visualization within the patient's thoracic cavity, repair or removal of the patient's natural valve, and, if necessary, attachment of a replacement valve in the natural valve position.

Of particular interest in the present application are techniques for the implantation of an atrioventricular valve that can be retracted or folded inside a delivery system or cannula for delivery through a less-invasive intercostal penetration to the desired place, particularly in a left atrium. Thereafter, the retracted valve is released, expanded, separated from the delivery system, and secured to the desired place with a minimally invasive technique. The same minimally invasive system can also deliver a medical device for drug delivery, energy delivery, and tissue ablation, among other applications.

Therefore, it would be desirable to provide a delivery system for delivering therapeutic means in a patient's heart comprising a heart valve configured to be releasably

folded inside a lumen of the delivery system through a percutaneous intercostal penetration of a patient's chest. The therapeutic means may also comprise a medical device that has radiofrequency or cryo-energy ablation capability.

One aspect of the present invention is to fabricate a stentless and/or supportless atrioventricular valve and a delivery system thereof that avoids the aforementioned disadvantages, wherein the valve comprises a singular membrane of biocompatible material that has at least two cusps configured to form a substantially tubular shape for use as an atrioventricular valve, and wherein the delivery system comprises a short apparatus for approaching the left atrium through a percutaneous intercostal penetration.

Summary of the Invention

One aspect of the present invention is to provide a stentless and/or supportless atrioventricular valve comprising a singular membrane of tissue or plastic material. In one embodiment, the valve has a sewing ring and at least two cusps hinged continuously from the inner opening of the sewing ring, wherein the cusps are an integral part of a continuum from the singular membrane configured or conformed to form a substantially tubular shape for use as an atrioventricular valve. In one embodiment, the substantially tubular form of the disclosed atrioventricular valve follows the "Function Follows Form" concept.

Another aspect of the present invention to fabricate a stentless and/or supportless atrioventricular valve with a singular membrane of tissue biomaterial that is chemically treated to reduce its antigenicity. Alternately, the singular membrane of biomaterial of the present invention is a synthetic plastic.

Another aspect of the present invention to provide a method of forming a stentless and/or supportless atrioventricular valve intended for attaching to a circumferential valve ring and papillary muscles of a patient comprising a singular membrane of biomaterial with at least two cusps, wherein either cusp has a semicircular tip edge joined by two generally straight side edges and wherein each straight side edge is trimmed and configured at an angle of about less than 20 degrees from a reference imaginary central longitudinal line of that cusp.

A preferred aspect of the present invention is to provide a delivery system and methods for minimally invasively delivering a medical device or an atrioventricular valve into the anterior of a patient's heart. In one embodiment, the delivery system has a securing mechanism for maintaining the system at a desired place during the operation,

wherein the securing mechanism may comprise a plurality of vacuum suction elements associated with an inflatable balloon.

In one embodiment, the sewing ring of the atrioventricular valve is made from a continuum of the singular membrane or is further reinforced by a sewing ring element to enhance the attachment of the sewing ring onto a heat valve annulus of a patient. In an alternate embodiment, the sewing ring element is made of a biocompatible material selected from a group consisting of non-biodegradable plastic material, biodegradable plastic material, non-biodegradable biological material, biodegradable biological material, and the like.

In another embodiment, the cusps further comprise texture element(s) at an edge portion of the cusps configured and adapted to extend the texture elements for connection to papillary muscles in a ventricle cavity when the sewing ring is sutured to an atrioventricular junction of a patient heart. In a further embodiment, the texture elements may be made of polyester, polytetrafluoroethylene fabric, polyurethane, silicone, or other suitable fabrics.

A further aspect of the invention is to provide a delivery system for accessing a left atrium of a patient through a cardiac wall, the delivery system comprising a cup balloon located at a distal section of the delivery system, wherein the cup balloon has a balloon rim configured for defining an isolated enclosure bordered by the balloon rim of the cup balloon and the cardiac wall.

Brief Description of the Drawings

Additional objects and features of the present invention will become more apparent and the invention itself will be best understood from the following Detailed Description of Exemplary Embodiments when read with reference to the accompanying drawings.

FIG. 1 is a sewing ring element comprising essentially flat side surfaces to be wrapped within a singular membrane of biomaterial for valve fabrication.

FIG. 2 is a singular membrane of biomaterial having a hole at about a central region of the membrane adapted for valve fabrication of the present invention.

FIG. 3 is another embodiment of the present invention comprising a pre-trimmed singular membrane of biomaterial having a hole at about a central region of the membrane adapted for valve fabrication.

FIG. 4 is a first step of the valve fabrication by laying a sewing ring element on top of the singular membrane of biomaterial.

FIG. 5 is a next step of the valve fabrication by wrapping a singular membrane around the sewing ring element.

FIG. 6 is a further step of the valve fabrication by inverting a periphery of the singular membrane through an opening of the sewing ring element.

FIG. 7 is another step of the valve fabrication by securing the singular membrane onto the sewing ring element.

FIG. 8 is one further step of the valve fabrication by aligning the potential wrinkles or folds adjacent the remote ends portion of the cusps.

FIG. 9 is still another step of the valve fabrication by trimming the cusps at a desired angle with reference to an imaginary central straight line of the cusp, wherein the valve is shown at an open position.

FIG. 10 is a cross-sectional view of section I - I of FIG. 8, illustrating the distal portion of a cusp comprising texture elements at edge portions of the cusps configured to extend the texture elements for connection to papillary muscles in a ventricle cavity when the sewing ring is sutured to an atrioventricular junction of a patient heart.

FIG. 11 is the atrioventricular valve shown at a close position.

FIG. 12A is a perspective view of an atrioventricular valve following the blood flow direction.

FIG. 12B is a perspective view of an atrioventricular valve against the blood flow direction.

FIG. 13 is a delivery system of the present invention for minimally invasively deploying a medical device to the interior of a body.

FIG. 14 is a cross-section view of the distal portion of a delivery system according to the principles of the present invention.

FIG. 15 is a front cross-sectional view of section II - II of FIG. 14, illustrating a cup balloon element with suction capability.

FIG. 16 is a preferred embodiment of the atrioventricular valve that is constrained with a minimal profile during a minimally invasive deployment stage.

FIG. 17 is an illustrative view of a medical device being delivered to an interior of a body via a minimally invasive manner.

Detailed Description of the Preferred Embodiments

Referring to FIGS. 1 to 17, what is shown is an embodiment of a stentless and/or supportless atrioventricular valve and a delivery system thereof comprising a singular membrane of tissue or plastic biomaterial. Most conventional heart valves are manufactured as stented valves. In the last few years, stentless heart valves with more flexible annular rings are available; however, those valves are still typically supported by sutures or clothes on the valve and/or between the cusps and the valve base. A commercially available pericardium valve made by suturing leaflets together to form a valve is not a "supportless valve" according to the present invention.

One embodiment of the invention relates to the "supportless" atrioventricular valve. The supportless atrioventricular valve is comprised of an anterior cusp and a posterior cusp, each cusp having two generally straight side edges that are joined at a semicircular tip edge, wherein each of the straight side edges is trimmed and configured at an angle of about 20 degrees or less, preferably between a range of 15 to 20 degrees, from a reference central longitudinal line of the cusp. The supportless atrioventricular valve has no additional support, such as a conventional stenting element made of metal or plastic material. The supportless atrioventricular valve is quite feasible for delivery to an implant site by a minimally invasive manner.

In another embodiment, a stentless atrioventricular heart valve made of a singular flexible membrane is described as follows. FIG. 1 shows a sewing ring element comprising essentially flat or straight side surfaces to be wrapped within a singular membrane of biomaterial for valve fabrication of the present invention. A sewing ring element 10 having a general configuration of circular, oval shape, D-shape, or other convenient shape may be made of rigid, semi-rigid or flexible biomaterial from synthetic polymer or biological tissue. In one embodiment, the sewing ring element 10 in FIG. 1 comprises a first top surface 12 bordered by a first inner edge (that is, the inner perimeter) 14 defining the ring opening 11 and a first outer edge 13 (that is, the outer perimeter), a second bottom surface 15 opposite of the first surface 12, wherein the first surface 12 and the second surface 15 are connected by a supporting member of the sewing ring element

10. The second surface 15 is bordered by a second inner edge (that is, perimeter) 16 defining the bottom ring opening 9 and a second outer edge or perimeter 17.

In one embodiment, the ring opening 11 at the first top surface 12 is identical in shape and size to the bottom ring opening 9. The ring 10 is conformed suitable for suturing or securing onto another material, such as a singular flexible membrane 20 of the present invention. In a particular embodiment, the configuration or shape of the first inner edge 12 may not necessarily match that of the second inner edge 16 while the configuration or shape of the first outer edge 13 may not necessarily match that of the second outer edge 17. The sewing ring opening of the present invention may be "D" shaped and matched by a correspondingly larger D-shaped external profile suitable for placing the atrioventricular valve in a patient heart. A circular, oval shaped or D-shaped ring opening that is flexible for replacing an atrioventricular valve is well known to a cardiac surgeon or skilled artisan.

The sewing ring element 10 further comprises an inner perimeter 14 including at least a straight side portion 19 thereof and an outer perimeter 13 having a straight side portion 18. The side portions 18, 19 may also be a non-straight configuration. In another alternate embodiment, the cross-section configuration of a sewing ring element may be square, circular, oval, D-shaped, trapezoidal, or other irregular shape.

In an illustrative embodiment, the sewing ring element may be made of a biocompatible material selected from a group consisting of non-biodegradable plastic material, biodegradable plastic material, non-biodegradable biological material, or biodegradable biological material. The sewing ring element may be textured, porous, or constructed of fabric components suitable for valve fabrication.

In the supportless atrioventricular valve embodiment, the sewing ring element of the present invention may be a virtual element or a temporary template. The "virtual element" is herein intended to mean an imaginary non-existing element that aids in better describing and assisting the valve fabrication process. The sewing ring element as a temporary template aid is intended to simplify the valve fabrication process, followed by disengaging the template from the finished valve. One example of the temporary template is made of a liquid soluble substance that is disengaged from the valve by dissolution or biodegradation.

FIG. 2 shows a singular membrane of biomaterial having a hole 26 with its border or perimeter 27 at about a central region of the membrane and a periphery region 35 (shown in FIG. 5) adapted for valve fabrication. The singular flexible membrane 20 has a

first membrane surface 28 and an opposite second membrane surface 29. The surface property/morphology of the surface 28 may be similar or different to that of the opposite membrane 29. Typically, the membrane surfaces 28, 29 are relatively smooth for intended valve fabrication purposes. In one embodiment, the membrane 20 is shaped like a typical rectangular singular sheet that is bordered by four edges 22, 23, 24, and 25 that are part of the periphery 35. In an alternate embodiment, the membrane may shape circularly, irregularly without recognizable edges, or in a special design configuration. The membrane 20 may be selected from biological tissue, a synthetic polymer or a synthetic protein matrix. The membrane of biological tissue may be chemically treated to reduce its antigenicity. The chemicals for treating biological tissue may include glutaraldehyde, formaldehyde, dialdehyde starch, polyepoxy compounds, or the like that are well known to one who is skilled in the art of chemical treatment. Further, the membrane of tissue may be pericardium tissue selected from a group consisting of equine, bovine, porcine, ovine, human, or other animals. The thickness of tissue membrane is preferred to be in the range of less than 0.1 mm up to about a few millimeters. The singular membrane 20 made of synthetic polymer may be selected from a group consisting of polyurethane, silicone, expanded polytetrafluoroethylene, fluoro-polymer, polyester, polyethylene, polypropylene or co-polymer thereof. The singular membrane of the present invention has adequate strength or mechanical properties suitable as a heart valve construct.

In an alternate embodiment, the singular flexible membrane may be pre-trimmed and shaped for a valve fabrication. FIG. 3 shows another embodiment of the present invention comprising a precut (that is, pre-trimmed) singular membrane 2 of biomaterial having a hole 3 at about a central region of the membrane adapted for valve fabrication. In one illustrative embodiment, the membrane 2 comprises a first major cusp member 4, a second major cusp member 5, a third minor cusp member 6, and a fourth minor cusp member 7. All cusp members are so pre-trimmed that the final fabricated configuration is suitable as a stentless and/or supportless atrioventricular valve apparatus. The first major cusp member 4 has a first side edge 4A, an opposite second side edge 4B, and a first end edge 4C, and a second end edge 4D. Further, the first major cusp member 4 has a first trimmed edge 4E and a second trimmed edge 4F. Similarly as shown in FIG. 3, the second major cusp member 5 has a first side edge 5A, an opposite second side edge 5B, and a first end edge 5C, and a second end edge 5D. Further, the second major cusp member 5 has a first trimmed edge 5E and a second trimmed edge 5F. Not all edges of the major cusp members 4, 5, or the minor cusp members 6, 7 are straight. The edges may be essentially straight or in other suitable curvature suitable for making the intended valve of the present invention.

A first group of the trimmed edges 4E, 5E of the present invention is trimmed and configured at an angle (θ) of about less than 20 degrees from a reference central longitudinal line and adapted to be a constituent of the posterior cusp 51 (as shown in FIG. 9). Similarly, the second group of the trimmed edges 4F, 5F of the present invention is trimmed and configured at an angle (β) of about less than 20 degrees from a reference central longitudinal line and adapted to be a constituent of the anterior cusp 52 (as shown in FIG. 9). The angle θ or β may preferably be in the range of about 15 to 20 degrees.

As shown in FIG. 3, the third minor cusp member 6 has two side edges 6A, 6B and an end edge whereas the fourth minor cusp member 7 has two side edges 7A, 7B and an end edge. As stated, any edge may be essentially straight or in other suitable curvature suitable for making the intended valve of the present invention.

To fabricate a stentless and/or supportless cardiac valve of the present invention, a hole 26 is created at about the center of the membrane 20, wherein the hole 26 (so-called the membrane opening) has a perimeter 27 that substantially matches the second inner edge or perimeter 16 of the ring element 10. FIG. 4 shows a first step of the valve fabrication by laying a sewing ring element 10 on top of the singular membrane 20 of biomaterial so as to substantially match the second ring opening 9 against the membrane opening 26. In an alternate fabrication process using a virtual element, this first step is skipped.

A plurality of sutures (either temporary sutures or permanent sutures) 31, 32, 33 or other securing mechanisms to fasten the membrane 20 onto the ring 10 are secured evenly at along the contacting zone between the membrane 20 and the second ring surface 15.

Thereafter, all edges (for example, edges 22, 23, 24, and 25 in FIG. 2; or the cusp members 4, 5, 6, and 7 in FIG. 3) or the periphery region 35 of the membrane 20 are picked up so as to wrap over the second bottom surface 15 of the ring 10 and to continue wrapping around the second outer edges 17, the outer straight side portion 18, and the first outer edge 13 of the sewing ring element 10. In one embodiment, FIG. 5 shows a picked-up membrane with the second membrane surface 29 facing exteriorly while the first membrane surface 28 facing interiorly. The periphery region portion 35 where all edges are picked and pulled close to each other is located at about the very top of the combined structure of the ring element 10 and membrane 20. FIG. 5 shows a next step of the valve fabrication by wrapping a singular membrane around the sewing ring element 10.

FIG. 6 shows a further step of the valve fabrication by inverting the periphery 35 of the singular membrane through an opening 11 of the sewing ring element 10 so as to

form a complete wrapping around the ring element 10. In other words, the singular membrane 20 hereby wraps over the first surface 12 of the ring element 10 and to continue wrapping around the first inner edge 14 and the second inner edge 16 of the sewing ring element 10. In one embodiment, FIG. 6 shows a fully wrapped membrane with the first membrane surface 28 facing exteriorly while the second membrane surface 29 facing interiorly. The portion of the membrane-covered sewing ring element is also known as the sewing ring 21 of the atrioventricular valve to be secured to the valvular annulus of a patient. There may be a few wrinkles or folds 38, 39 at about the sewing ring 21 as a result of inverting the membrane 20 through the ring element opening 11.

FIG. 7 shows another step of the valve fabrication by securing the singular membrane onto the sewing ring element. To configure the singular membrane 20 more suitable as a functional cardiac valve of the present invention, the membrane 20 is slightly stretched and re-positioned over the ring 10 so that essentially all the wrinkles 38, 39 are grouped at two opposite ends 36, 37 of the ring element 10. In other words, the majority portion of the membrane 20 over the ring element 10 away from the two opposite ends 36, 37 is essentially free of wrinkles.

As shown in FIG. 7, a plurality of sutures 41, 42, 43 or other securing mechanisms are placed substantially equally spaced at along the contacting zone of the membrane and the first ring surface 12. One embodiment of securing the membrane onto the ring element is to suture or stitch the membrane at the second surface 15 to the membrane at the first surface 12 by passing a suture through the ring 10 itself. In the "supportless" embodiment, the ring 10 is to subsequently dissolved after assembly so that a derived sewing ring 21 is made of the membrane material alone.

FIG. 8 shows one further step of the valve fabrication by aligning the potential wrinkles adjacent the remote ends portion of the cusps, whereas FIG. 9 shows still another step of the valve fabrication by trimming the cusps at a desired angle with reference to an imaginary central straight line of the cusp(s). This trimming step may be omitted and substituted by a pre-trimmed singular membrane 2 as shown in FIG. 3.

By following the above-described procedures, a stentless and/or supportless atrioventricular valve can also be fabricated from a pre-trimmed singular membrane 2. The periphery portion (including cusp members 4, 5, 6, and 7) of the membrane 2 is inverted and passes through the ring opening 11 of the sewing ring element 10. The edge pairs (for example, a pair of edges 4B and 6B; a pair of edges 5B and 6A; a pair of edges 5A and 7A; and a pair of edges 4A and 7B) are secured together to form a substantially

tubular shape for use as the atrioventricular valve apparatus. In one embodiment, the posterior cusp may comprise the cusp member 7 and its adjacent secured portions of the cusp members 4 and 5. Similarly, the anterior cusp may comprise the cusp member 6 and its adjacent secured portions of the cusp members 4 and 5. The cusp members 4 and 5 are trimmed essentially symmetrical; i.e., the edges 5C, 5D, 5E, and 5F are equivalent counterparts of the edges 4C, 4D, 4E, and 4F, respectively.

FIG. 9 shows a stentless and/or supportless sewing ring 21 with a trimmed membrane. In one illustration of a bi-leaflet valve, the periphery portion 35 is trimmed and configured to include a posterior cusp 51 and an anterior cusp 52. The sewing ring 21 of the present invention comprises an opening defined by a perimeter including at least a first and a second straight side portions thereof. An anterior cusp 52 is configured hinged continuously from the first straight side portion while a posterior cusp 51 is configured hinged continuously from the second straight side portion opposite the anterior cusp 52, wherein the anterior cusp and the posterior cusp are an integral part of a continuum from the singular membrane 20 with a common commissure between remote ends 61 of the anterior cusp 52 and the posterior cusp 51. Collectively, the anterior cusp 52 and the posterior cusp 51 are carried over from the outer surface 18 of the sewing ring element 10 and then hinged continuously along the inner surface 19.

As shown in FIG. 9, the membrane-covered sewing ring 21 is formed by an inverted flange portion of the combined cusps 51, 52 located at about the sewing ring place 21 that is configured to shape the sewing ring opening, wherein the flange portion from the cusps 51, 52 is an integral part of a continuum from the singular membrane 20.

The atrioventricular valve of the present invention may further comprise a third cusp located between the anterior cusp 52 and the posterior cusp 51, wherein the third cusp hinged continuously from a third straight side portion of the perimeter 14 and wherein the third cusp is an integral part of a continuum from the singular membrane 20 without sutured commissure between any two remote ends of the anterior cusp, the posterior cusp and the third cusp. A cardiac valve with two cusps (that is, a bileaflet valve) or three cusps (that is, a trileaflet valve) is well known to an ordinary cardiac surgeon or one who is skilled in the art.

The anterior cusp 52 or the posterior cusp 51 of the atrioventricular valve of the present invention has a generally semicircular or curved edge portion to enable it projecting deeply into the ventricle cavity when the sewing ring 21 is sutured to an atrioventricular junction of a patient heart. In one embodiment as illustrated in FIG. 8, the

anterior cusp 52 has a semicircular or curved tip edge 65 and two generally straight side edges 63, 64 that are joined at the tip edge 65, wherein each (63 or 64) of the straight side edges is trimmed and configured at an angle (β) of about less than 20 degrees from a reference central longitudinal line 66 of the anterior cusp 52 (FIG. 9).

Similarly, in another embodiment as illustrated in FIG. 8, the posterior cusp 51 may have a semicircular or curved tip edge 55 and two generally straight side edges 53, 54 that are joined at the tip edge 55, wherein each of the straight side edges 53, 54 is trimmed and configured at an angle (θ) of about less than 20 degrees from a reference central longitudinal line 67 of the anterior cusp 51 (shown in FIG. 9). The edges at about the cusp joint 61 is so trimmed and configured to exert certain degree of tension for proper valve close and open operations. This tensioned cusp joint 61 is equally true for the case of using a pre-trimmed singular flexible membrane 2.

FIG. 10 shows a cross-sectional view of section I - I of FIG. 8, illustrating the distal portion of a cusp comprising texture elements at edge portion(s) of the cusps configured to extend the texture element(s) for connection to papillary muscles in a ventricle cavity when the sewing ring is sutured to an atrioventricular junction of a patient heart. For illustration purposes, a portion of the posterior cusp 51 is further shown in FIG. 10 to indicate a plurality of optional openings 73, 74 and an end region 72 of the posterior cusp 51 covered with a texture element 75 made of silicone rubber (Silastic™), cloth (usually Dacron™), or cloth coated with polytetrafluoroethylene (Teflon™) or other fabric. A conventional method of securing the texture element onto the cusp may include bonding, stitching, gluing, suturing or the like.

In an alternate embodiment starting with a pre-trimmed singular membrane 2, the cusp member 7, the right-side portion of the cusp member 4, and the right-side portion of the cusp member 5 are to be joined to form the posterior cusp 51 shown in FIG. 10, wherein the cusp members 76, 77, and 78 in FIG. 10 are equivalent counterparts of those referred above. The remote portions 72 of the cusp members 76, 77, 78 are joined by the texture element 75. The remaining portions of the edges of the cusp members 76, 77, 78 away from the remote portions 72 may not be secured together and thus may form the openings such as 73, 74.

In securing together the three cusp members of the membrane 2 to form either a posterior cusp or an anterior cusp, more tension is applied to the edge 4E rather than the opposite edge 4A (FIG. 3). This higher tension is generally true for the edges 4F, 5E, and 5F than their corresponding opposite edges 4B, 5A, and 5B, respectively during the valve

fabrication process. As a result of appropriate tension arrangements to each individual edge and cusp members, the finished cusp 51 is configured to have lower tension on the cusp member 77 as compared to the adjacent cusp members 76 and 78 and enables the cusps 51, 52 of the present invention to function as a competent atrioventricular heart valve.

The anterior cusp 52 and/or the posterior cusp 51 of the present invention may comprise texture elements at edge portions of the cusps configured to extend the texture elements for connection to papillary muscles in a ventricle cavity when the sewing ring is secured to an atrioventricular junction of a patient's heart. The anatomy of the atrioventricular valves and the subvalvular apparatus of a patient can be found in any medical reference textbook (for example, MITRAL VALVE, edited by H Boudoulas and CF Wooley, published by Futura Publishing, NY 2000). The texture elements are formed integral with the cusps 51, 52 and are provided with integral attachment portions at ends 72 remote from the cusps for suturing to the papillary muscles. In one embodiment, the supportless atrioventricular valve apparatus is secured at an atrioventricular junction using a dissolvable or biodegradable material.

Angelini and associates (*Anatomy of the Mitral Valve* in MITRAL VALVE, edited by H Boudoulas and CF Wooley, published by Futura Publishing, NY 2000), entire contents of which are incorporated herein by reference, teach the mitral valvar complex being attached proximally at the left atrioventricular junction and, distally, through the papillary muscles, to the myocardial wall of the left ventricle. Proper action of the complex depends on normal function and integration of each of the components. Therefore, it is one object of the present invention to provide an atrioventricular valve fabricated from a singular flat membrane of biomaterial adapted to mimic the natural mitral function.

The general configuration of either the posterior cusp 51, the anterior cusp 52 or the third cusp in a trileaflet valve apparatus may be slightly concave to exhibit adequate support when secured to the papillary muscles in a ventricle cavity upon deployment.

FIG. 9 shows an atrioventricular valve at an open position while FIG. 11 shows the valve at its close position. At a valve close position, the ventricle is contracted. The cusp is under quite tension because the remote end of the cusps is still attached to the papillary muscle. The cusps joint section 61 so constructed according to the principles of the present invention enables the valve to close promptly at systole.

FIG. 12A shows a perspective view of an atrioventricular valve following the blood flow direction (that is, the valve is open), while FIG. 12B shows a perspective view of an atrioventricular valve against the blood flow direction (that is, the valve is closed). During an atrial relaxation phase, the atrioventricular valve cusps are open toward to the ventricle cavity along with the blood flow direction (arrow 57). During a ventricular contraction phase, the atrioventricular cusps tend to push back against the blood flow direction (arrow 58). The atrioventricular valve according to the present invention may also be flexible and retractable/foldable within a delivery apparatus for minimally invasive delivery purposes.

FIG. 13 shows a delivery system of the present invention or delivery means for minimally invasively deploying a medical device to the interior of a body, particularly through a percutaneous intercostal penetration. It is one aspect of the invention to provide a method for minimally invasively delivering an atrioventricular valve made of a singular membrane of tissue into a patient comprising folding said valve within a lumen of a delivery system or delivery means for delivering through a cardiac wall into a left atrium of the patient. The delivery system (also known as "delivery means" for delivering a medical device into a body of a patient) may comprise a delivery apparatus 80 and an inner medical device 107 that is slidably inserted within a lumen 95 of the delivery apparatus 80, wherein the inner medical device may serve as the delivery means for delivering the atrioventricular valve of the present invention.

The "inner medical device" of the present invention is meant to indicate a device that could be inserted through a lumen of the delivery apparatus 80 for advancing into an interior cavity or a patient's heart for therapeutic or diagnostic purposes, including delivering a heart valve, delivering energy to treat tissue, delivering a drug, or the like. A delivery system of the present invention comprises a delivery apparatus 80 having a shaft 89, the shaft 89 having a distal end 81, a distal opening 88A, a proximal end 82, and at least one lumen 95 between the distal end 81 and the proximal end 82. The delivery apparatus 80 also comprises a distal section 83 that is used to releasably secure the distal end 81 at about a cardiac wall during delivering the inner medical device.

The delivery apparatus 80 comprises a handle or handpiece 84 that is attached to the proximal end 82 of the shaft 89. The delivery apparatus 80 also comprises a fluid infusion system 85 with a fluid infusion control mechanism 85A for inflating a cup balloon 90 (see FIG. 14) securely attached at the distal section 83 of the apparatus 80. Further, the apparatus 80 comprises a suction mechanism 86 with a suction control mechanism 86A for releasably attaching the cup balloon 90 onto the cardiac wall of a

patient. The "cup balloon" of the present invention is a cup, cone, or half-a-ball shape configured for defining an isolated enclosure bordered by the balloon rim of the cup balloon and the cardiac wall. There is an elongated lumen 95 within the delivery apparatus 80 having a distal opening 88A and a proximal opening 88B, wherein a proximal receiving element 87 on the apparatus 80 with a locking mechanism 87A is for introducing an inner medical device 107 of the present invention into the interior cavity of a patient's heart. The atrioventricular valve of the present invention is generally characterized by its softness and collapsibility radially for delivery by the inner medical device 107.

The delivery apparatus 80 may be made from plastic material, metal or composite material. In one embodiment, the delivery apparatus may be made of the material selected from the group consisting of polyethylene, polypropylene, polycarbonate, nylon, polytetrafluoroethylene, polyurethane, stainless steel, Nitinol, titanium, polyimide, polyester, and the like. Similarly, the inner medical device may be made of the material selected from the group consisting of polyethylene, polypropylene, polycarbonate, nylon, polytetrafluoroethylene, polyurethane, stainless steel, Nitinol, titanium, polyimide, polyester, and the like.

FIG. 14 shows a cross-section view of the distal section 83 of the delivery apparatus 80 of a delivery system according to the principles of the present invention. In one embodiment, after the apparatus 80 is delivered to adjacent a desired location at the cardiac wall, the rim of the cup balloon 90 in a circular or continuous loop manner is deployed and the suction ports 93 are activated so that the outermost rim 99 in a circular or continuous loop manner of the cup balloon 90 is firmly and suckedly attached to the cardiac wall, defining an attachment rim surface bordered by a balloon inner wall 92B and a balloon outer wall 92A. The inflating fluid is infused to the balloon 90 via a fluid passageway 91 which is a part of the overall fluid infusion system 85.

The cup balloon 90 in FIG. 14, upon being inflated, defines a cup-like enclosure or compartment that is isolated from the surrounding environment. The balloon may be made of any typical elastomeric material, such as silicon, latex, polyurethane, mixture or copolymer thereof, or the like. Like a party balloon, when the balloon 90 is inflated, the balloon tends to expand both radially and longitudinally outwardly (shown by an arrow 98). The balloon construction and its use as balloon angioplasty in cardiovascular applications are well known to one who is skilled in the art.

The cup balloon of the delivery system is preferably inflated with a saline solution to avoid the possibility of introducing into the patient an air embolism in the event that the balloon ruptured. The balloon should be inflated to a pressure sufficient to form an isolated enclosure to prevent outflow of blood into the surrounding. An intermediate pressure in the order of 10 mmHg to 100 mmHg or more is preferable. The suction or vacuum pressure for the plurality of suction ports is generally in the range of -5 to -100 mmHg.

FIG. 15 shows a front cross-sectional view of section II - II of FIG. 14, illustrating the balloon 90 with a plurality of suction ports 93 at its rim 99. Each suction port 93 is connected to the suction mechanism 86 via a suction passageway 94 individually or collectively.

The stentless and/or supportless atrioventricular valve 21 of the present invention may be folded inside a lumen 97 of the inner medical device 107 as shown in FIG. 16. Other folded shapes or folding/retraction patterns of an implant, including the atrioventricular valve 21, inside the inner medical device 107 is also within the scope of the present invention.

FIG. 17 shows an illustrative view of an inner medical device 107 being delivered to the left atrium 106 of a patient, wherein the patient's heart 100 is positioned to show the left atrium 106 and atrium wall 101. In operation, the delivery apparatus 80 of a delivery system of the present invention having a cup balloon arrangement 90 at the distal section of the delivery apparatus 80 is deployed through a percutaneous intercostal penetration. The delivery apparatus 80 may be introduced through a cannula or trocar 104 positioned in one of percutaneous intercostal penetrations, the cannula or trocar having a proximal end disposed outside of the patient and a distal end disposed within the chest. A general minimally invasive procedure is well known to ordinary clinicians who are skilled in the art. Examples are U.S. Pat. No. 5,972,030 and No. 5,613,937 to Garrison et al., entire contents of which are incorporated herein by reference.

After the distal end 81 of the delivery apparatus 80 touches the cardiac wall (or in other cases, a pericardium sac wall), the cup balloon 90 is deployed for its balloon rim 99 to intimately contact the wall while suction or vacuum is applied to the suction ports 93 adapted for creating an isolated working enclosure about the distal section 83 of the apparatus 80. In one embodiment, a first inner medical device of a sharp scalpel or having a sharp-end is introduced through the opening 88B to create a slit or opening on the wall (either pericardium sac wall, cardiac wall or both). The scalpel is thereafter removed from

the delivery system. In a subsequent embodiment, a second inner medical device of an ablation catheter with at least one electrode may be introduced through the proximal opening 88B. The ablation catheter may be used to ablate one or more pulmonary veins for treating atrial fibrillation. U.S. Pat. No. 6,217,576, No. 6,241,727 and No. 6,290,697 co-invented by one of the applicants, the entire contents of which are incorporated herein by reference, teach a catheter probe and methods for treating focal atrial fibrillation in pulmonary veins. Treating atrial fibrillation by ablating one or more pulmonary veins is well known to an electrophysiologist who is skilled in the art.

The method for minimally invasively delivering a stentless and/or supportless atrioventricular valve made of a singular membrane of tissue into a patient, the method may further comprise the step of removing at least a portion of a patient's atrioventricular valve by means of a cutting tool introduced through a percutaneous intercostal penetration and through an internal penetration on the cardiac wall. The method may further comprise fastening the atrioventricular valve within the left atrium by means of an instrument introduced through the percutaneous intercostal penetration and through the internal penetration. In one embodiment, the percutaneous intercostal penetration is created in a right lateral portion of a patient's chest.

A conventional procedure for approaching pulmonary veins in the left atrium is by intravascular catheterization from a femoral vein or artery through the cardiac septal which separates the right atrium and the left atrium. The disadvantages of an intravascular procedure include a long tortuous route (usually a catheter of longer than one meter) that is dangerous and tedious; limited catheter size (usually up to 6 or 7 French catheter size) that can't hold a folded atrioventricular valve; and a leaking cardiac septal that is difficult to re-seal.

In an alternate embodiment, a third inner medical device having a folded/retracted stentless and/or supportless atrioventricular valve of the present invention at its distal end is introduced through the proximal opening 88B. After the distal end reaches at about the atrioventricular annulus, the valve is deployed out of the distal end 96 of the inner medical device. Securing a heart valve onto the annulus location using a minimal invasive technique is well known to one who is skilled in the art and constitutes no part of the present invention.

The present invention discloses a method of forming a stentless and/or supportless atrioventricular valve intended for attaching to a circumferential valve ring and papillary muscles of a patient as afore-mentioned described. The method may comprise the steps of

(a) selecting a singular membrane of biomaterial and an essentially flat sewing ring element, wherein said membrane comprises a hole in about a central region of said membrane and a periphery region, and wherein said sewing ring element comprises an outer diameter and an inner diameter defining an inner straight side portion, an outer straight side portion, a bottom side portion and a top side portion, said hole matching said inner diameter of said sewing ring element; (b) placing said sewing ring element on top of said membrane conformed to align said hole with the inner diameter of said ring element; (c) securing said membrane onto said sewing ring element at a contact region of said membrane to the bottom side portion of the ring element; (d) flapping the membrane around the outer straight side portion and the top side portion of said ring element; (e) inserting the periphery of said membrane through the inside diameter of the ring element configured to form a sewing ring with an inverted membrane around all of the bottom side portion, outer straight side portion, top side portion and inner straight side portion; and (f) trimming the membrane to form at least two cusps suitable for replacing in a diseased or dysfunctional atrioventricular valve of the patient.

Furthermore, the present invention discloses a method for minimally invasively delivering a stentless and/or supportless atrioventricular valve made of a singular membrane of tissue into a patient, said method comprising folding the valve within a lumen of delivery means for delivering through a cardiac wall into a left atrium of the patient. The method may comprise the steps of (a) advancing a delivery apparatus of the delivery means through a percutaneous intercostal penetration and reaching the cardiac wall, wherein said delivery apparatus comprises a cup balloon at a distal section of the delivery apparatus having a plurality of suction ports at a balloon rim of said cup balloon; (b) deploying the cup balloon and applying suction to said plurality of suction ports to create an isolated enclosure around a distal region of the delivery apparatus; (c) introducing a sharp-end inner medical device inside said delivery apparatus toward the cardiac wall and creating a passthrough opening on said wall; (d) withdrawing the sharp-end inner medical device from said delivery apparatus; (e) introducing a second inner medical device having the folded atrioventricular valve through the passthrough opening into the left atrium; and (f) delivering the atrioventricular valve suitable out of said second inner medical device for implanting at a heart valve location.

In operation, a delivery apparatus 80 of the present invention is deployed through an intercostal penetration. The delivery apparatus may be introduced through a cannula or trocar 104 positioned in one of percutaneous intercostal penetrations, the cannula or trocar having a proximal end disposed outside of the patient and a distal end disposed within the chest.

In a minimally invasive procedure, a method for percutaneously delivering an atrioventricular valve for treating a leaky valve may comprise the steps of: (1) delivering the atrioventricular valve to the anatomical valvular position percutaneously during a delivery phase; (2) deploying the atrioventricular valve during a deployment phase; and (3) placing and securing the atrioventricular valve at about the anatomical valvular annulus. The method may further comprise forming a plurality of percutaneous intercostal penetrations in a patient's chest, each of the percutaneous intercostal penetrations being within an intercostal space between two adjacent ribs, wherein the atrioventricular valve is delivered through one of the percutaneous intercostal penetrations.

In addition to performing atrioventricular valve repair and replacement, the techniques of the invention also facilitate surgical intervention into other regions of the heart and great vessels. The delivery system and methods described above may be used to form an opening directly into the left ventricle, right atrium, or right ventricle, or into a great vessel such as the aorta, superior vena cava, inferior vena cava, pulmonary artery, or pulmonary vein, for surgical intervention in such cavities. For example, a penetration may be made in the wall of the aorta with a vacuumed enclosure, and the aortic valve may be repaired or replaced with a bioprosthesis, using techniques and delivery systems like those described above for atrioventricular valve replacement.

Moreover, the device systems and methods of the invention also facilitate intracardiac procedures such as repair of atrial or ventricular septal defects, electrophysiological mapping and ablation of the myocardium, electrophysiological mapping and ablation of the pulmonary veins, myocardial drilling, and other procedures. Furthermore, delivery systems may be introduced through an opening into the heart or great vessel and advanced therefrom into vessels such as the coronary arteries to perform procedures such as angioplasty, atherectomy, coronary artery bypass grafting, or the pulmonary veins to perform procedures such as atrial fibrillation ablation.

An alternate aspect of the present invention is to provide a method of treating atrial fibrillation using a medical device with at least one radiofrequency electrode, the method comprising introducing the medical device through an intercostal penetration and an opening on a cardiac wall into a left atrium of a patient, wherein radiofrequency energy is provided through the at least one electrode to ablate at least one pulmonary vein in the left atrium.

In one embodiment, a trocar may be placed at the intercostal penetration for the medical device to pass through. Further, the opening on the cardiac wall may be created

by a delivery system having a delivery apparatus and a sharp-end inner medical device for creating said opening, the delivery apparatus comprising a cup balloon located at a distal section of said delivery apparatus configured for defining an isolated enclosure bordered by said cup balloon and said cardiac wall. Alternately, the delivery apparatus further comprises a plurality of suction ports located along a balloon rim of said cup balloon adapted for releasably securing said rim onto said cardiac wall.

From the foregoing description, it should now be appreciated that a stentless and/or supportless atrioventricular valve comprising a singular membrane of tissue with at least two cusps and methods of delivery in a minimally invasive manner have been disclosed. While the invention has been described with reference to a specific embodiment, the description is illustrative of the invention and is not to be construed as limiting the invention. Various modifications and applications may occur to those who are skilled in the art, without departing from the true spirit and scope of the invention, as described by the appended claims.

Claims:

1. A stentless atrioventricular valve comprising a singular membrane of tissue, said valve having a sewing ring comprising an opening defined by a perimeter including at least a first and a second straight side portions thereof, an anterior cusp hinged continuously from said first straight side portion, a posterior cusp hinged continuously from said second straight side portion opposite said anterior cusp, wherein said anterior cusp and said posterior cusp are an integral part of a continuum from said singular membrane configured to form a substantially tubular shape for use as the atrioventricular valve.

2. The stentless atrioventricular valve of claim 1, wherein the sewing ring is formed by an inverted flange portion of the combined cusps located at about the sewing ring that is configured to shape said sewing ring opening, wherein said flange portion from the cusps is an integral part of a continuum from said singular membrane.

3. The stentless atrioventricular valve of claim 1, wherein the anterior cusp and the posterior cusp further comprise texture elements at edge portions of the cusps configured to extend said texture elements for connection to papillary muscles in a ventricle cavity when the sewing ring is sutured to an atrioventricular junction of a patient heart.

4. The stentless atrioventricular valve of claim 1 further comprising a third cusp located between the anterior cusp and the posterior cusp, wherein the third cusp hinged continuously from a third straight side portion of the perimeter, said third cusp is an integral part of a continuum from said singular membrane configured to form a substantially tubular shape for use as the atrioventricular valve.

5. The stentless atrioventricular valve of claim 1, wherein the anterior cusp or the posterior cusp has a generally semicircular edge portion to enable it projecting deeply into said ventricle cavity.

6. The stentless atrioventricular valve of claim 1, the posterior cusp having a semicircular tip edge and two generally straight side edges that are joined at said semicircular tip edge, wherein each of said straight side edges is trimmed and configured

at an angle of about less than 20 degrees from a reference central longitudinal line of said posterior cusp.

7. The stentless atrioventricular valve of claim 1, the anterior cusp having a semicircular tip edge and two generally straight side edges that are joined at said semicircular tip edge, wherein each of said straight side edges is trimmed and configured at an angle of about less than 20 degrees from a reference central longitudinal line of said anterior cusp.

8. The stentless atrioventricular valve of claim 1, wherein said sewing ring opening is D-shaped, and is matched by a correspondingly larger D-shaped external profile suitable for placing said atrioventricular valve in a patient heart.

9. The stentless atrioventricular valve of claim 1 or 4, wherein the sewing ring is formed by an inverted flange portion of the posterior and anterior cusps at about the sewing ring, the inverted flange portion being wrapped around and secured to a flat sewing ring element configured to shape said sewing ring opening, wherein said flange portion from the cusps is an integral part of a continuum from said singular membrane.

10. The stentless atrioventricular valve of claim 9, wherein the inverted flange portion is wrapped around and stitched to the flat sewing ring element.

11. The stentless atrioventricular valve of claim 9, wherein the sewing ring element is made of a biocompatible material selected from a group consisting of non-biodegradable plastic material, biodegradable plastic material, non-biodegradable biological material, or biodegradable biological material.

12. The stentless atrioventricular valve of claim 3, wherein the texture elements are made of polyester or polytetrafluoroethylene fabric.

13. The stentless atrioventricular valve of claim 3, wherein the texture elements are formed integral with the cusps and are provided with integral attachment portions at ends remote from the cusps for suturing to the papillary muscles.

14. The stentless atrioventricular valve of claim 1, wherein said membrane of tissue is chemically treated to reduce its antigenicity.

15. The stentless atrioventricular valve of claim 14, wherein said membrane of tissue is pericardium tissue selected from a group consisting of equine, bovine, porcine and ovine.

16. A method of forming a stentless atrioventricular valve intended for attaching to a circumferential valve ring and papillary muscles of a patient comprising:

selecting a singular membrane of biomaterial and an essentially flat sewing ring element, wherein said membrane comprises a hole in about a central region of said membrane and a periphery region, and wherein said sewing ring element comprises an outer diameter and an inner diameter defining an inner straight side portion, an outer straight side portion, a bottom side portion and a top side portion, said hole matching said inner diameter of said sewing ring element;

placing said sewing ring element on top of said membrane conformed to align said hole with the inner diameter of said ring element;

securing said membrane onto said sewing ring element at a contact region of said membrane to the bottom side portion of the ring element;

flapping the membrane around the outer straight side portion and the top side portion of said ring element;

inserting the periphery of said membrane through the inside diameter of the ring element configured to form a sewing ring with an inverted membrane around all of the bottom side portion, outer straight side portion, top side portion and inner straight side portion;

trimming the membrane to form at least two cusps suitable for replacing in a diseased or dysfunctional atrioventricular valve of the patient.

17. The method of forming a stentless atrioventricular valve of claim 16, wherein at least one of said at least two cusps has a semicircular tip edge and two generally straight side edges that are joined at said semicircular tip edge, wherein each of said straight side edges is trimmed and configured at an angle of about less than 20 degrees from a reference central longitudinal line of said cusp.

18. The method of forming a stentless atrioventricular valve of claim 16 further comprising a step of removing the ring element.

19. The method of forming a stentless atrioventricular valve of claim 16, wherein said membrane of biomaterial is tissue that is chemically treated to reduce its antigenicity.

20. The method of forming a stentless atrioventricular valve of claim 16, wherein said membrane of biomaterial is a synthetic polymer.

21. A method for minimally invasively delivering a supportless atrioventricular valve made of a singular membrane of tissue into a patient, said method comprising folding said valve within a lumen of delivery means for delivering said valve through a cardiac wall into a left atrium of the patient.

22. The method of claim 1, wherein said valve comprising a sewing ring having an opening defined by a perimeter including at least a first and a second straight side portions thereof, an anterior cusp hinged continuously from said first straight side portion, a posterior cusp hinged continuously from said second straight side portion opposite said anterior cusp, wherein said anterior cusp and said posterior cusp are an integral part of a continuum from said singular membrane configured to form a substantially tubular shape for use as the supportless atrioventricular valve.

23. The method of claim 2, wherein said singular membrane of tissue is chemically treated to reduce antigenicity of said membrane.

24. The method of claim 3, wherein said membrane of tissue is pericardium tissue selected from a group consisting of equine, bovine, porcine, and ovine.

25. The method of claim 1 further comprising steps of:

(a) advancing a delivery apparatus of the delivery means through a percutaneous intercostal penetration and reaching the cardiac wall, wherein said delivery apparatus comprises a cup balloon at a distal section of the delivery apparatus having a plurality of suction ports at a balloon rim of said cup balloon;

(b) deploying the cup balloon and applying suction to said plurality of suction ports to create an isolated enclosure around a distal region of the delivery apparatus;

(c) introducing a sharp-end inner medical device inside said delivery apparatus toward the cardiac wall and creating a passthrough opening on said wall;

(d) withdrawing the sharp-end inner medical device from said delivery apparatus;

(e) introducing a second inner medical device having the folded supportless atrioventricular valve through the passthrough opening into the left atrium; and

(f) delivering the atrioventricular valve suitable out of said second inner medical device for implanting at a heart valve location.

26. The method of claim 1 wherein the delivery means is introduced through a cannula positioned in a percutaneous intercostal penetration.

27. The method of claim 1 further comprising a step of removing at least a portion of a patient's atrioventricular valve by means of a cutting tool introduced through a percutaneous intercostal penetration and through an internal penetration on the cardiac wall.

28. The method of claim 7 further comprising fastening the supportless atrioventricular valve within the left atrium by means of an instrument introduced through the percutaneous intercostal penetration and through the internal penetration.

29. The method of claim 8 wherein the supportless atrioventricular valve is introduced through a cannula positioned in the percutaneous intercostal penetration.

30. The method of claim 7 wherein the percutaneous intercostal penetration is created in a right lateral portion of a patient's chest.

31. A delivery apparatus for accessing a left atrium of a patient through a cardiac wall, said delivery apparatus comprising a cup balloon located at a distal section of said delivery apparatus, wherein said cup balloon having a balloon rim configured for defining an isolated enclosure bordered by said balloon rim of said cup balloon and said cardiac wall.

32. The delivery apparatus of claim 11, wherein said delivery apparatus further comprises a plurality of suction ports located along the balloon rim of said cup balloon adapted for releasably securing said balloon rim onto said cardiac wall.

33. The delivery apparatus of claim 12, wherein a suction pressure of the plurality of suction ports is in the range of -5 to -100 mmHg.

34. The delivery apparatus of claim 12, wherein the cup balloon is made of a material selected from a group consisting of silicone, polyurethane, latex, and mixture thereof.

35. The delivery apparatus of claim 11, wherein a pressure for inflating said cup balloon is in the range of 10 to 100 mmHg.

36. The delivery apparatus of claim 11, wherein the delivery apparatus is made of a material selected from a group consisting of polyethylene, polypropylene, polycarbonate, nylon, polytetrafluoroethylene, polyurethane, stainless steel, Nitinol, titanium, polyimide, and polyester.

37. A method of treating atrial fibrillation using a medical device with at least one radiofrequency electrode, the method comprising introducing said medical device through an intercostal penetration and an opening on a cardiac wall into a left atrium of a patient, wherein radiofrequency energy is provided through said at least one electrode to ablate at least one pulmonary vein in the left atrium.

38. The method of claim 17, wherein a trocar is placed at the intercostal penetration for said medical device to pass through.

39. The method of claim 17, wherein the opening on the cardiac wall is created by a delivery system having a delivery apparatus and a sharp-end inner medical device for creating said opening, the delivery apparatus comprising a cup balloon located at a distal section of said delivery apparatus configured for defining an isolated enclosure bordered by said cup balloon and said cardiac wall.

40. The method of claim 19, wherein said delivery apparatus further comprises a plurality of suction ports located along a balloon rim of said cup balloon adapted for releasably securing said rim onto said cardiac wall.

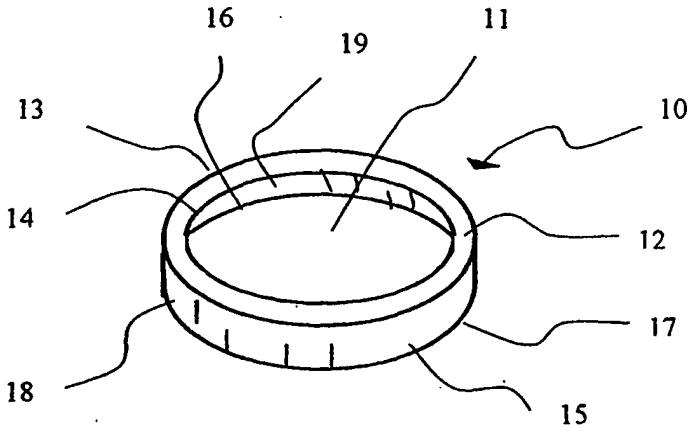

FIG. 1

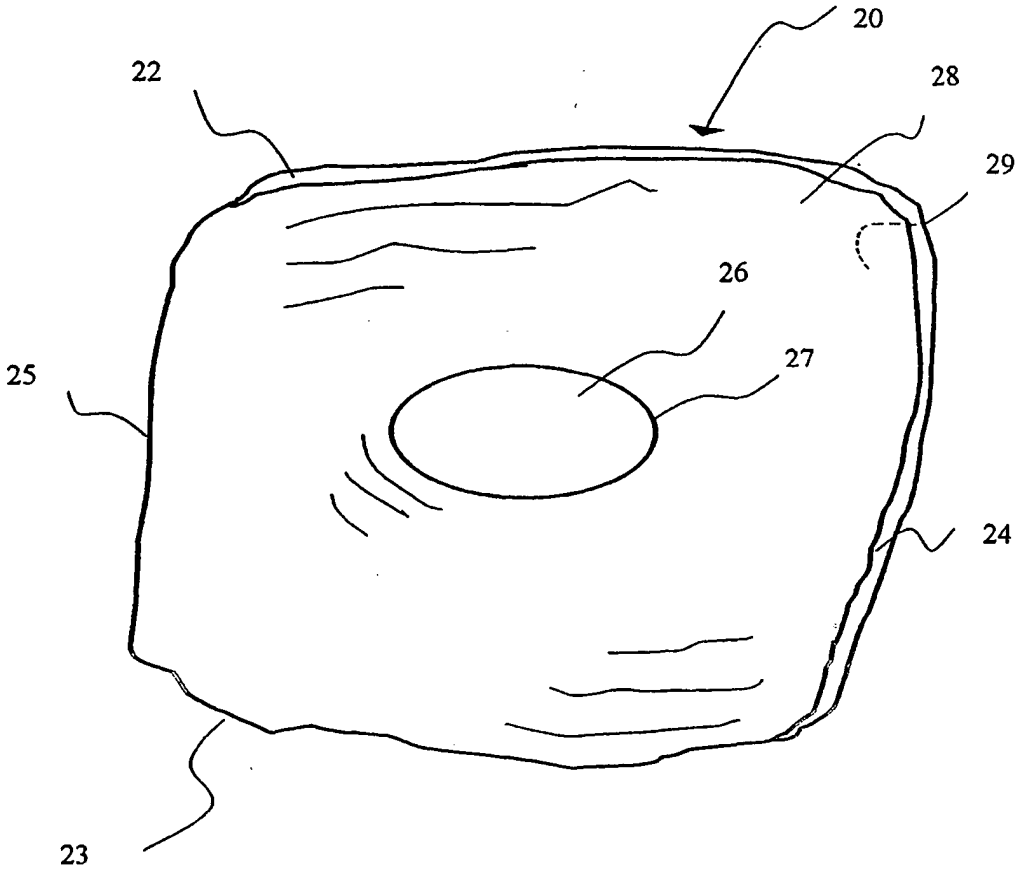

FIG. 2

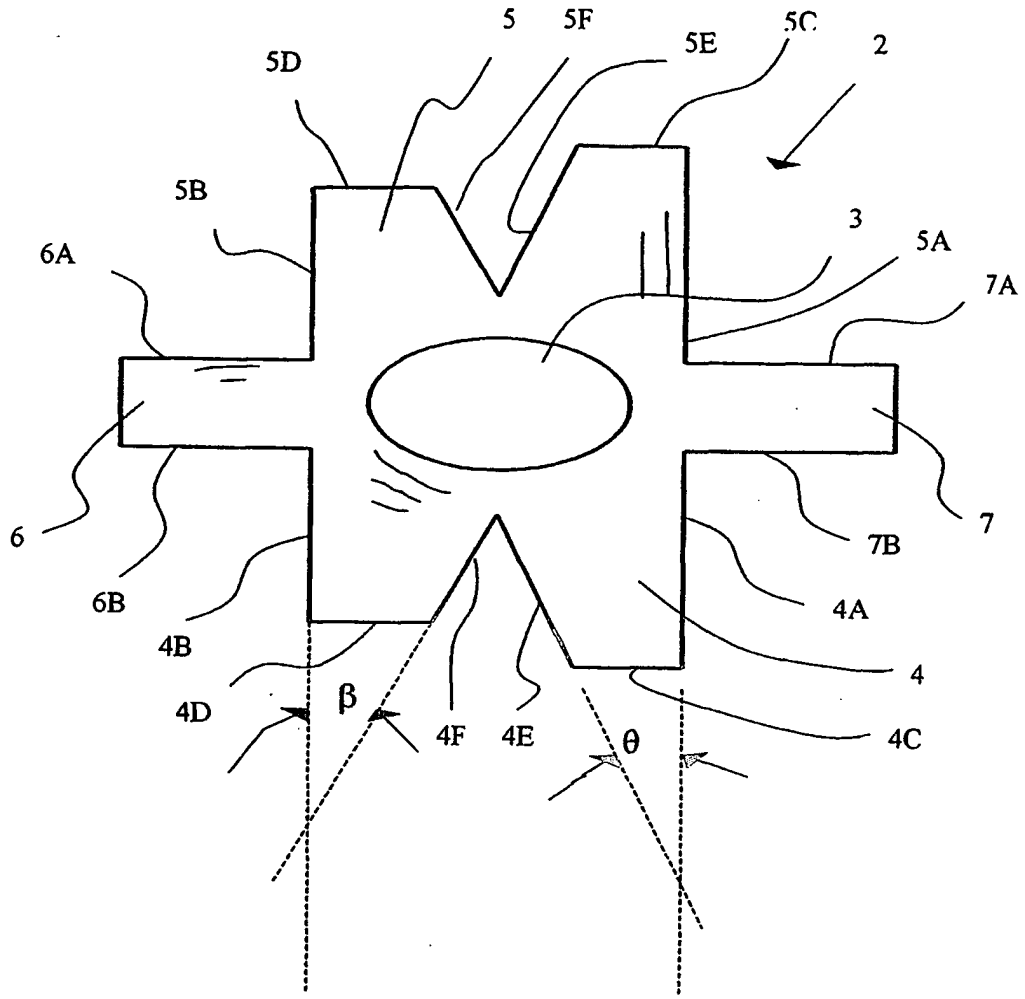

FIG. 3

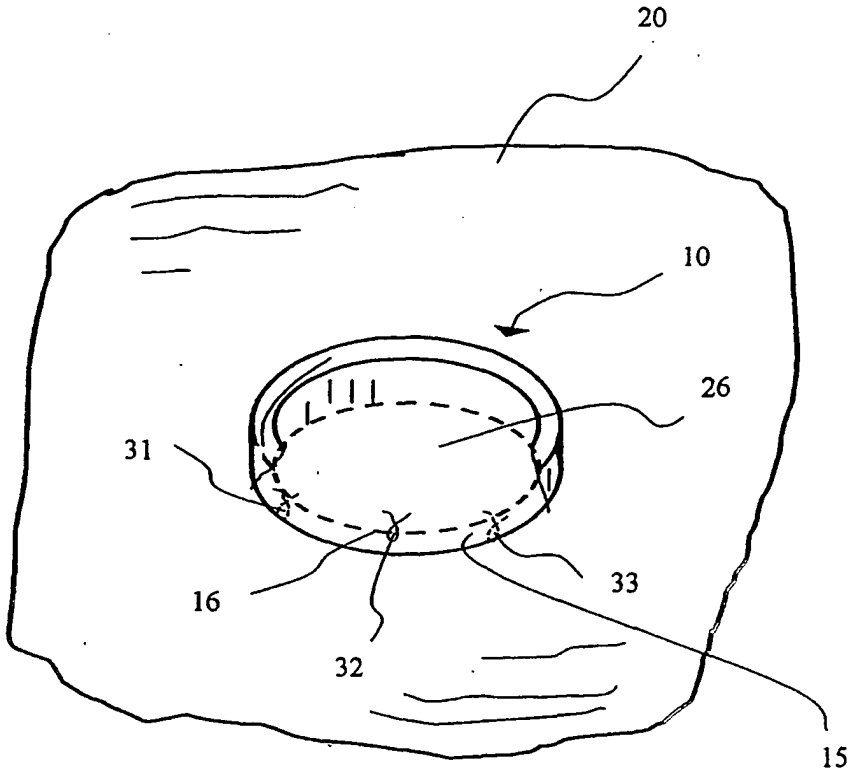

FIG. 4

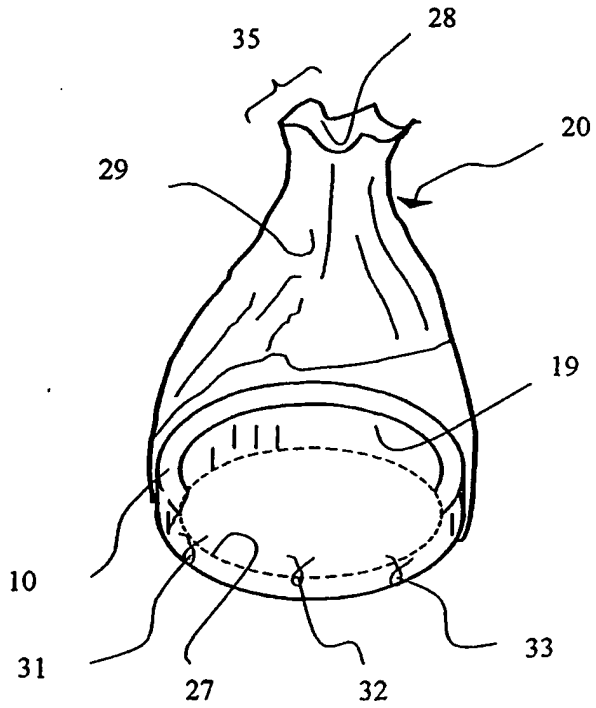

FIG. 5

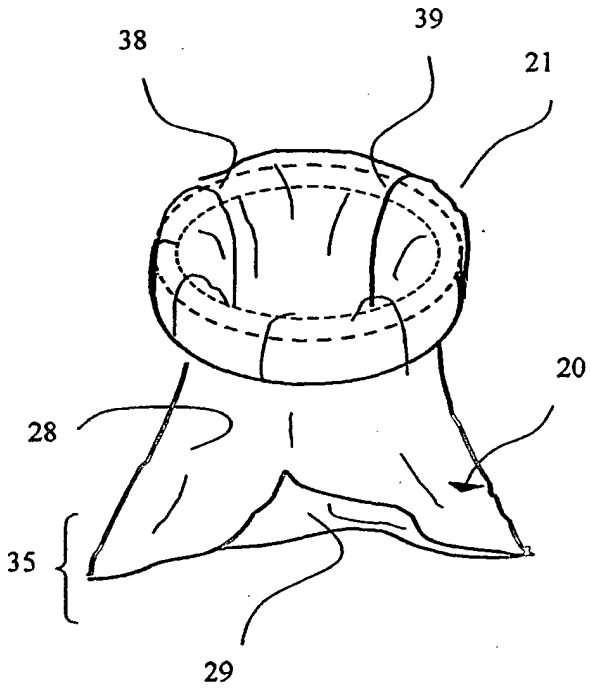

FIG. 6

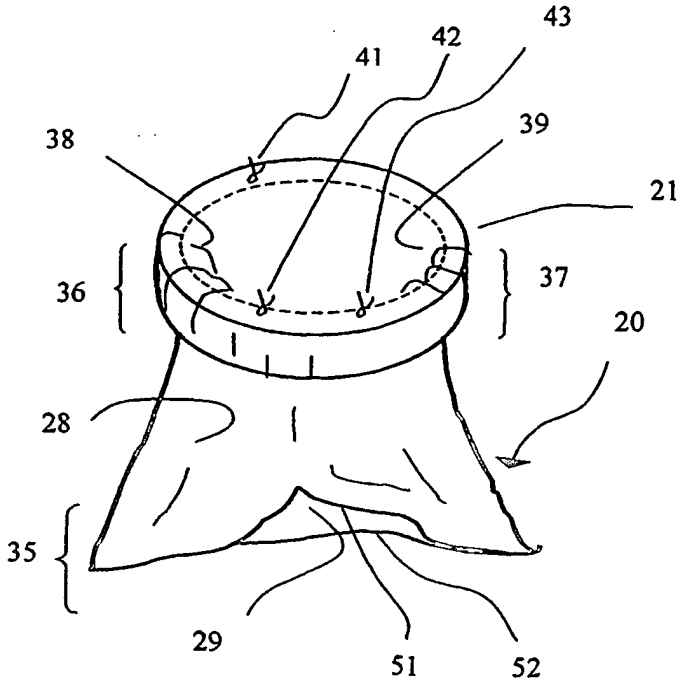

FIG. 7

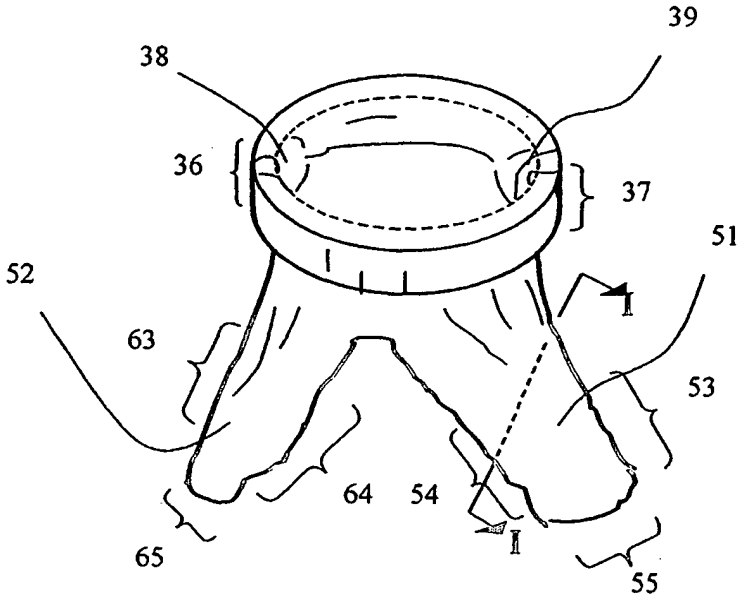

FIG. 8

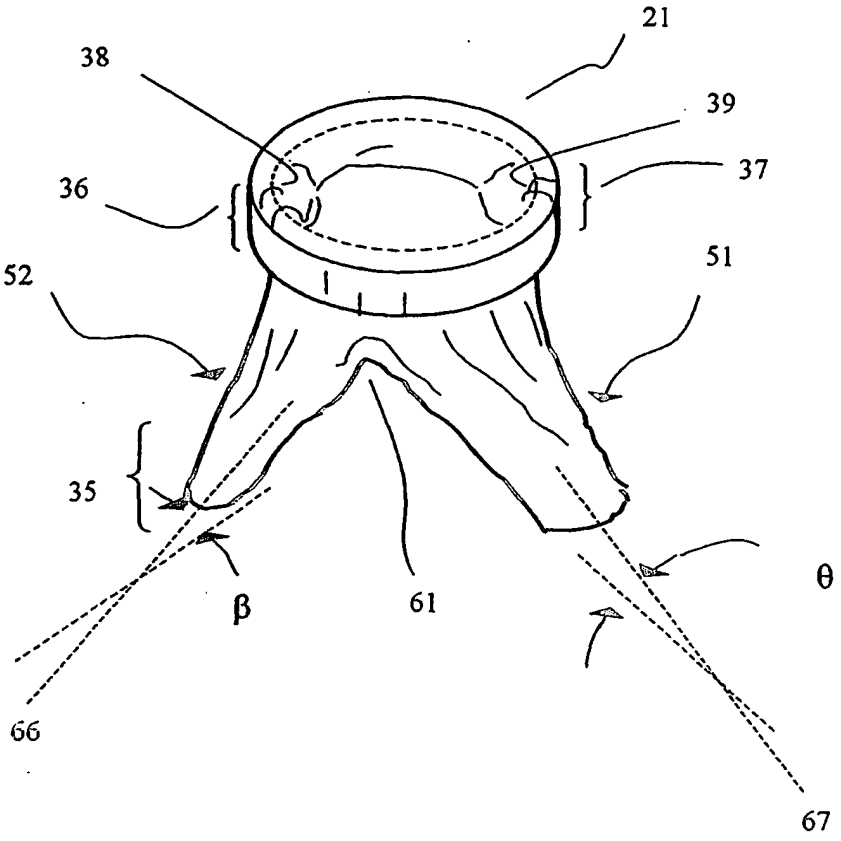

FIG. 9

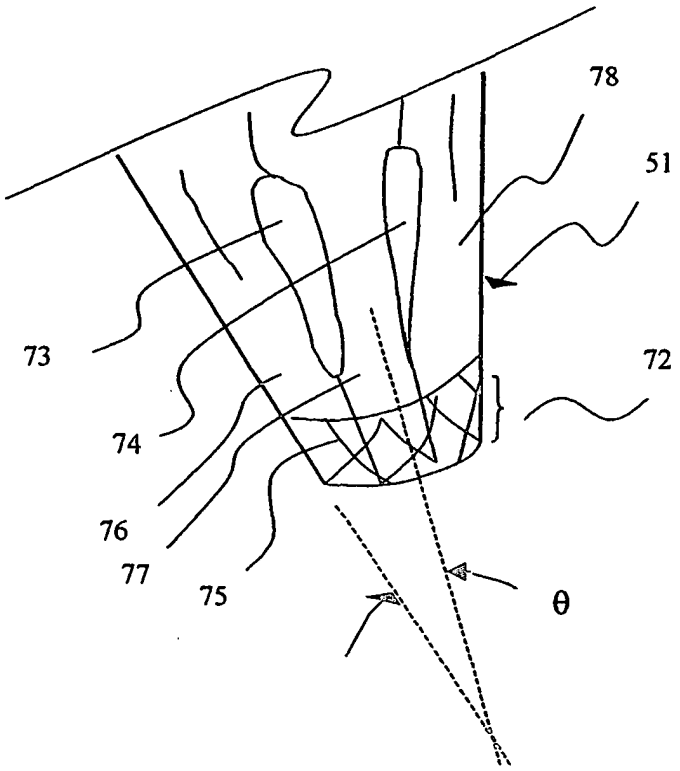

FIG. 10 section I-I

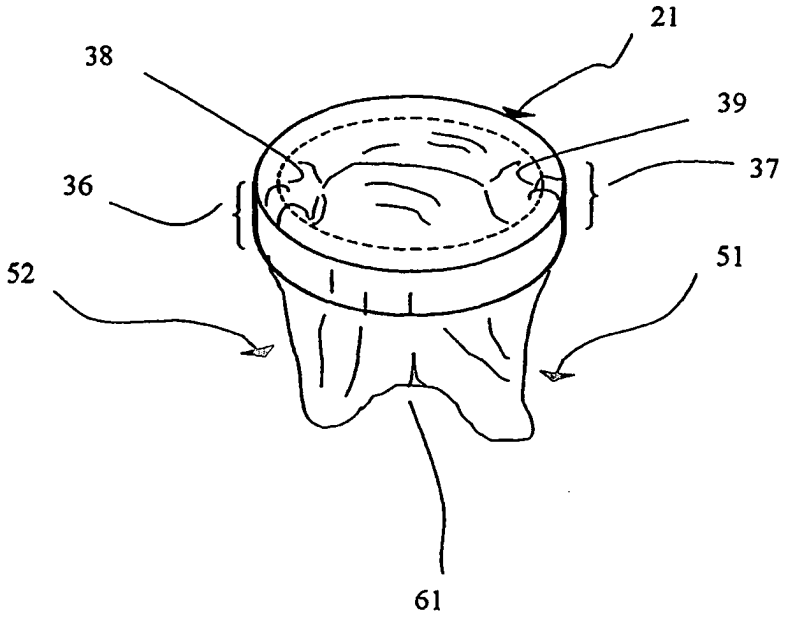

FIG. 11

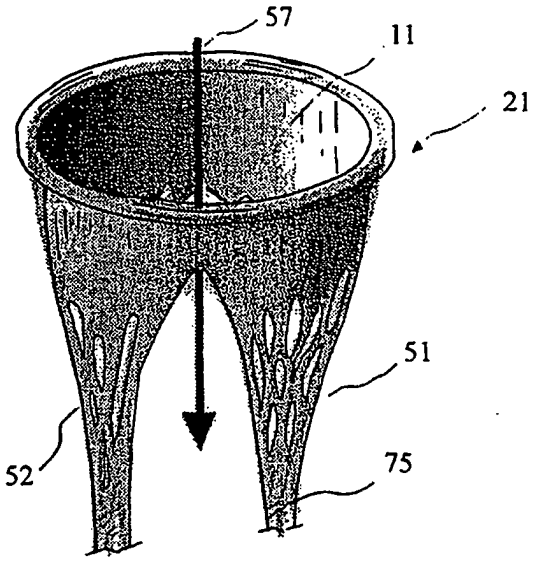

FIG. 12A

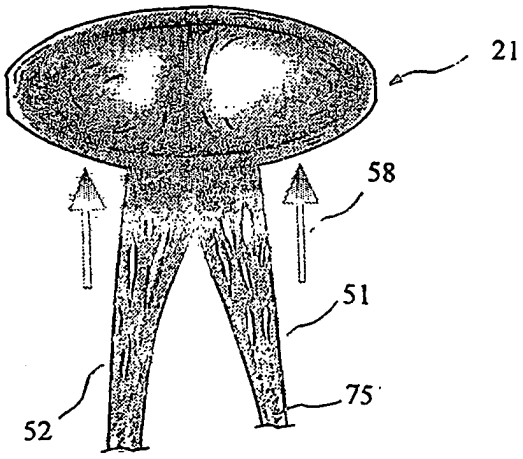

FIG. 12B

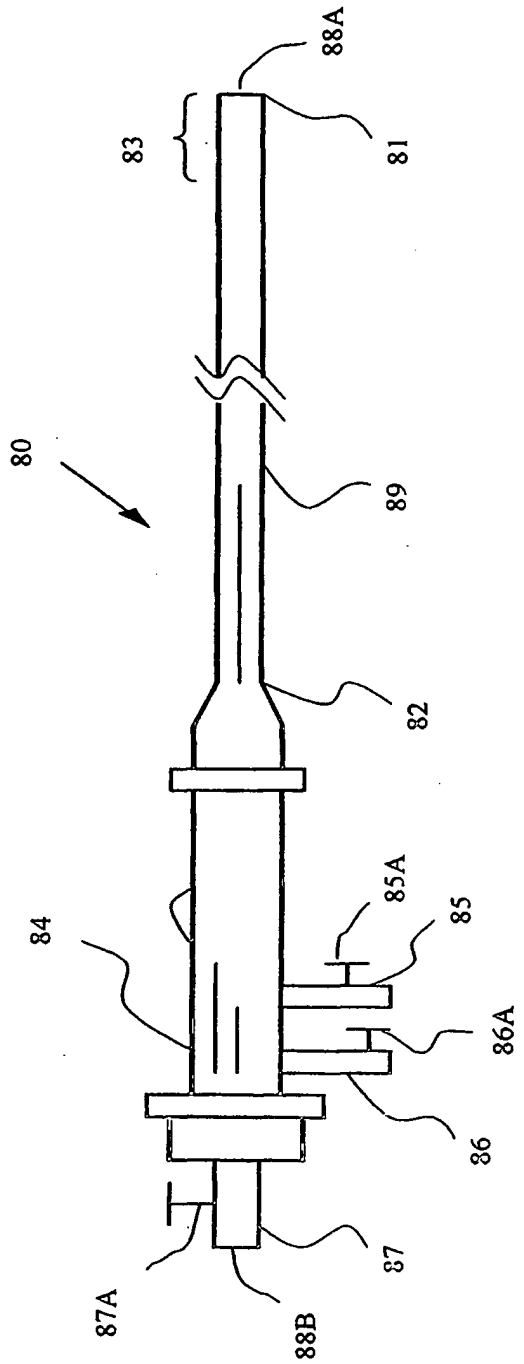

FIG. 13

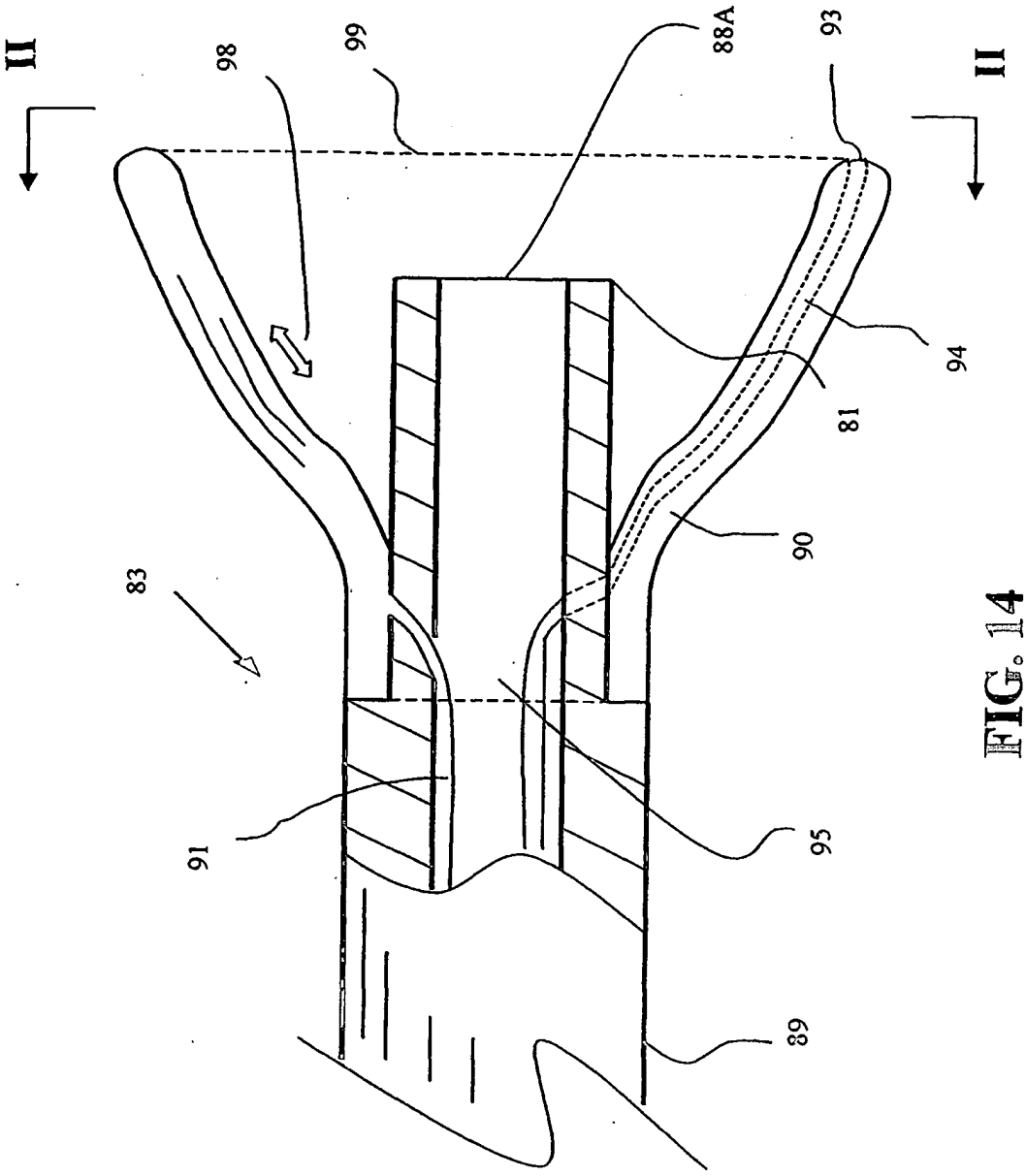

FIG. 14

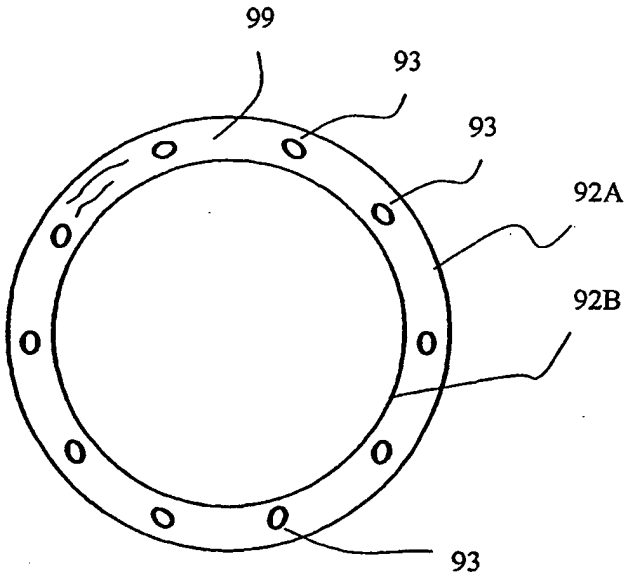

FIG. 15 section II-II

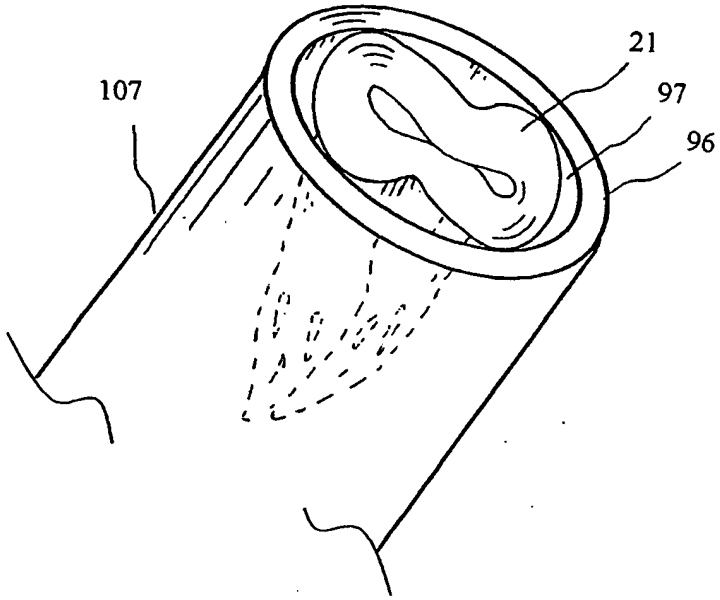

FIG. 16

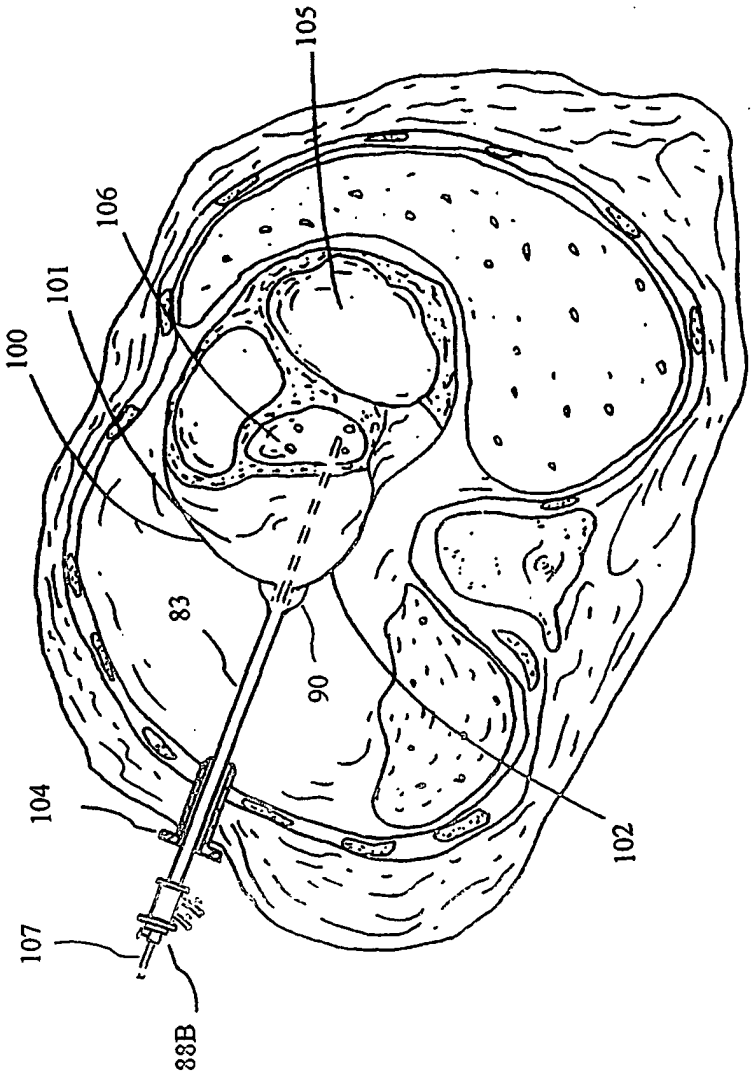

FIG. 17

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/18375

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 824 067 A (GROSS JEFFREY M) 20 October 1998 (1998-10-20) column 4, line 47 - line 53	1-3,5-20 4
X Y	US 5 156 621 A (NAVIA JOSE A ET AL) 20 October 1992 (1992-10-20) column 4, line 21 - line 37 column 5, line 6 - line 8 figure 2	1,2,14, 15 4
X	US 5 415 667 A (FRATER ROBERT W M) 16 May 1995 (1995-05-16) column 4, line 39 - line 47 figures 1,2	1-5,8, 11-14

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 March 2004	06. 07. 2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Franz, V

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Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/18375

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/037227 A (WHEATLEY DAVID JOHN ;UNIV GLASGOW (GB)) 8 May 2003 (2003-05-08) figure 8	1
A	US 6 358 277 B1 (DURAN CARLOS M G) 19 March 2002 (2002-03-19) the whole document	1-20
A	EP 0 276 975 A (OVIL YOEL) 3 August 1988 (1988-08-03) the whole document	1-20
A	US 3 739 402 A (KAHN P ET AL) 19 June 1973 (1973-06-19) the whole document	1-20
A	US 5 554 184 A (MACHIRAJU VENKAT R) 10 September 1996 (1996-09-10) the whole document	1-20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/18375

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 21-30, 37-40
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-20

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Claims Nos.: 21-30,37-40

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-20

Stentless atrioventricular valve comprising a singular membrane of tissue and a sewing ring and method of its production.

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2. claims: 31-36

Delivery apparatus comprising a cup balloon.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 03/18375

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
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